Remarks/Arguments

Reconsideration and allowance are respectfully requested in light of the following remarks.

Upon entry of this amendment claims 1-3, 11, 18, 41, 43, 44, 58-62, 95, 96, 98-109 and 111 would now be pending, claims 4-10, 12-17, 19-40, 42, 45-57, 63-94, 97 and 110 having been cancelled. Thus, the total number of pending claims after entry of the amendment will have been further reduced.

Claim 43 has been amended to direct the claimed method to treatment of the known conditions of atherosclerosis, pancreatitis, hypercholesterolemia and hyperlipoproteinemia. Support for the claims resides, *inter alia,* in prior claims 54-57. No new matter has been added. Entry of the amendment is respectfully requested.

Claims 43-44, 56, 58-60, 96, 99, 101 and 103-107 stand rejected under 35 U.S.C. 112, first paragraph as not being enabled for all disease states characterized by high low density lipoprotein particles (LDL) or cholesterol levels. This rejection is respectfully traversed.

The Office Action acknowledges that the specification and claims do enable methods of treating disease states characterized by high low density lipoprotein particles (LDL) or cholesterol levels selected from atherosclerosis, pancreatitis, and hyperlipoproteinemia.

Claims 43 has been amended to recite these disease states specifically and has also be amended to recite hypercholesterolemia, recited in original claim 56. The Office Action asserts that the treatment of hypercholesterolemia is not enabled based on a 1991 abstract (Vega et al, *Circulation,* 1991 Jul;84(1):118-28) and its statement that "the mechanisms underlying hypercholesterolemia ... are not well understood." However, regardless of the fundamental level of understanding recited in the cited literature, since 1991, a number of promising drugs

have been identified (HMG-CoA reductase inhibitors (aka statins)) which function by reducing endogenous cholesterol synthesis and which are being used to treat this disease state. Thus, with the recognition that HMG-CoA reductase inhibitors can be used to treat hypercholesterolemia, skilled workers now would recognize and accept that compounds with the ability to upregulate LDL receptor synthesis also would have utility for treating this disease state by virtue of their working on an inter-related mechanism for reducing cholesterol. Applicants submit that claim 43 limited to the specific disease states previously recited in claims 54-57 thus is enabled.

Claims 1-2, 11, 18, 41, 61-62, 95, 98, 100, 102, 108, 109 and 111 stand rejected for obviousness-type double patenting over claims 1-3 and 6-8 of U.S. 6,121,304; while all of the remaining claims, except for claim 3, *i.e.,* claims 43-44, 54-60, 96, 101, 103 and 106-107 stand rejected for obviousness-type double patenting over claims 1-3, 7, 10-18,and 25-332 of US 6,417,176. These rejections are respectfully traversed.

With respect to the rejection based on the '304 patent, applicants submit a Terminal Disclaimer to facilitate an allowance of the rejected claims. By submitting the Terminal Disclaimer, applicants do not concede that the claims have been, or could be properly rejected as being unpatentable for obviousness-type double patenting in view of the patent referenced in the Terminal Disclaimer.

With respect to the rejection based on the '176 patent, applicants traverse the rejection based on the following.

In the first place, the claims of the '176 patent are directed to certain arylsulfonanilide **phosphate derivatives**. There is no analogous structure in the compounds used in the claimed methods and none is identified in the office action. In addition, in the compounds of the '176 patent claims, none of the substituents covalently bonded directly to the sulfonanilide nitrogen can be a heteroaryl group. In contrast, the method claims of the present invention require use of

a class of compounds in which an "optionally substituted heteroaryl" is bonded directly to a "sulfonanilide nitrogen." As a result, there is absolutely no overlap between any claim of the '176 patent and any of the pending claims. Furthermore, nothing in the entire specification of the '176 patent, let alone in the claims themselves on which the rejection must be solely based, suggests making any of the significant structural changes that would have to be made to obtain the structure of the compounds used in the recited methods. Notably, the '176 patent is not used as a basis for rejecting the pending compound and composition claims on this ground.

The obviousness-type double patenting rejection citing the '176 patent is thus based solely on the fact that the disease states treated by the respective therapeutic methods overlap. That alone however falls woefully short of establishing the obviousness of using the recited/required compounds for treating such disease states. The fact that other compounds exist for treating certain types of diseases surely does not make obvious every other method for treating those same diseases with patentably distinct compounds. However, the obviousness type double patenting rejection that is presented based on the '176 patent is tantamount to that particular position. The rejection is not sustainable on that theory and must be withdrawn.

Reconsideration and the allowance of the pending claims are thus respectfully requested.

Respectfully submitted,

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